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| EXAMINER | |
|---|---|
| KAPUSHOC, STEPHEN THOMAS | |
| **ART UNIT** | **PAPER NUMBER** |
| 1634 | |

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/785,981 | KIM ET AL. | |
| | Examiner | Art Unit | |
| | Stephen Kapushoc | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-3 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3 is/are rejected.

7)☒ Claim(s) 1 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-3 are pending and examined on the merits.

### *Information Disclosure Statement*

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### *Claim Objections*

2. Claim 1 is objected to because of the following informalities: line two of the claim recites 'growth specific gene', where the plural 'growth specific genes' may be more appropriate. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are unclear because of the term 'a probe' in claim 1. It is unclear how a single probe would be capable of analyzing the multiple genes specifically expressed in the muscle and fat tissues of swine.

Claim 2 is unclear because of the phrase 'the probe DNA comprises the nucleotide sequences'. It is unclear if the applicant intends a single contiguous nucleic acid probe molecule that is SEQ ID NOs 1-5.

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the revised interim guidelines on written description published January 5, 2001 in the Federal Register, Volume 66, Number 5, page 1099-1111 (also available at www.uspto.gov).

The invention is drawn to a cDNA chip capable of detecting 'growth specific' genes in the muscle and fat tissues of swine (claims 1-3).

When the claims are analyzed in light of the specification, the instant invention encompasses a wide variety of genes and transcripts for which there is no written

description. The cDNA chip of claims 1-3 encompasses probes capable of detecting any 'growth specific' gene that is expressed in the muscle and fat tissue of swine under any conditions, such as different physiological or pathological conditions. Such probes would encompass nucleic acids corresponding to any gene that is expressed at any level in swine tissue. Furthermore, since the claims are broadly drawn using 'comprising' language, they encompass chips which have full length coding sequences, allelic variants (such as genes with single nucleotide polymorphic variants, insertions, and deletions), and splice variants of the genes of which SEQ ID NOs 1-5 are fragments. Since SEQ ID NOs 1-5 as disclosed in the specification are only partial coding sequences, they do not provide adequate written description for the broad genus encompassed by even claim 2.

The specification discloses only that 5 'growth specific' genes were identified by analyzing the hybridization of target DNA (Cy-3 and Cy-5 labeled cDNA from muscle and fat tissues of Kagoshima Berkshire swine; p.8 – Preparation example 2: Preparation of target DNA and hybridization) to an array consisting of 4434 ESTs (p.7 – Preparation example 1: Preparation and array of probe DNA) from Kagoshima Berkshire. The specification does not disclose any SEQ ID NOs corresponding to the 4434 ESTs that were used in the swine cDNA probe. The specification does not disclose any hybridization characteristics (e.g. found more highly expressed in fat sample than in muscle sample) that allow for the identification of a 'growth specific' gene, and discloses only SEQ ID NOs: 1-5 as 'growth-related genes'.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, there is no disclosure of nucleotide sequences by SEQ ID NO of any probe structures or EST sequences used to creat the array disclosed in the specification (p.7 – Preparation example 1: Preparation and array of probe DNA). For example, the specification does not provide any disclosure as the nucleotide sequences of genes or transcripts that would be expected to hybridize to the disclosed array used to identify 'growth specific' genes. Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, there is no disclosure of the identifying characteristics of any 'growth specific' genes or ESTs used in the array disclosed for identifying 'growth specific' genes.

Furthermore, the Examiner's search of SEQ ID NOs 1-5 did reveal any identifying characteristics that indicate these five disclosed nucleotide sequences are in some way representative of 'growth specific' genes in swine. SEQ ID NO: 1 has a high degree of similarity to a mouse gene (GenBank Locus MUSEFTU); SEQ ID NO: 2 shows similarity to swine myosin heavy chain 2b (eg GenBank Locus AB025261); SEQ ID NO: 3 shows highest similarity to a human cDNAs (eg GenBank Locus BG031674); SEQ ID NO: 4 shows highest similarity to a human alpha-actin mRNA (eg GenBank Locus HUMACTASK); SEQ ID NO: 5 does not show substantial similarity to a gene or

transcript in the prior art. Taken together, the analysis of SEQ ID NOs 1-5 therefore does not reveal any consistent identifiable characteristics that would aloow one of skill in the art to identify other genes or transcripts, or even the sequences of SEQ ID NOs 1-5, as 'growth specific' genes expressed in the fat and muscle tissue of swine.

In conclusion, the limited information supplied by the instant specification (i.e. SEQ ID NOs: 1-5, hybridization to a swine array with probes from genes expressed in the muscle and fat tissues of swine) is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of a functional cDNA chip for the screening and functional analysis of growth specific genes at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (1995) (US Patent 5,474,796).

The claims of the instant application are broadly drawn to a chip for the screening and analysis of swine genes. Brennan teaches a microarray that contains 10-mer

polynucleotides spotted at a discrete location such that the total array represents every possible permutation of 10-mer oligonucleotide (col. 9, lns. 48-55). Such an array would inherently comprise probes capable of detecting genes expressed in swine.

Regarding claim 1, the array of Brennan would inherently be capable of detecting genes, including any 'growth specific' genes, expressed in the muscle and fat tissues of swine (relevant to claim 1)

Regarding claim 2, the comprehensive nature of the 10-mer array of Brennan would make the array thus capable of detecting any genes or transcripts related to SEQ ID NOs 1-5, asserted in the instant application to be 'growth specific' genes from swine (p.11 of the instant specification). Furthermore, because the array of Brennan includes all 10-mer probes, such an array would also include probes the combinations of which would comprise the nucleotides sequences set forth in SEQ ID NOs 1-5.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipates by Yamamoto et al (2001).

Yamamoto et al teaches an analysis of swine genomic DNA by Southern blot analysis. The reference teaches a membrane (which is a substrate) containing immobilized swine genomic DNA, wherein the DNA is digested with restriction enzymes and separated on a 1% agarose gel prior to transfer to the solid support (Fig 1; p.3309, left col., lns.11-22). The immobilized swine genomic DNA necessarily includes probes capable of detecting growth specific genes in the muscle and fat tissues of swine.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Yao et al (2002).

Yao et al teaches the construction of a cDNA library from porcine skeletal muscle (p.213, ln.5).

Regarding claim 1, Yao et al teaches that RNA was isolated from the skeletal muscle of pigs, amplified by RT-PCR, and then the collection of fragments was cloned into a plasmid vector (p.213, lns.12-23). The reference also teaches the analysis of the cDNAs by Southern blot analysis. Yao et al teaches that aliquots of plasmid DNA from the library are digested to liberate the insert, separated on a 1% agarose gel, then blotted onto a Zeta-probe membrane (p.214 – Southern blot analysis; p.215, last paragraph). The membrane containing the separated library (Fig 1) is thus a cDNA chip (i.e. a substrate upon which cDNA probes are immobilized). The immobilized probes include a mixture of probes derived from swine, and would thus be comprised of probes suitable for the screening and analysis of 'growth specific' genes expressed in tissues of swine.

11. Claim 1 and 3 are rejected under 35 U.S.C. 102(a) as being anticipated by Bai et al (2003).

Bai et al teaches a porcine skeletal muscle cDNA microarray. The reference teaches that inserts from two porcine skeletal muscle λZAP-Express cDNA libraries (p.11, left col., lns.8-11) were amplified to create probe DNA that was immobilized on a glass slide (p.11, left col., lns.37-50).

Regarding claim 1, the array taught by Bai et al is a cDNA chip (a collection of cDNA-specific probes immobilized on a substrate of CMT-GAPS coated slides), and would be comprised of probes capable of detecting genes and transcripts, including growth specific' genes, expressed in swine muscle and fat tissues (p.11 – Red-white muscle microarray hybridization).

Regarding claim 3, Bai et al teaches a kit (i.e. a collection of compositions) including an array of swine cDNAs (p.11 – Construction of porcine skeletal muscle cDNA microarray) which would necessarily be comprised of probes for growth specific genes, as well as probe cDNA created using the CyScribe First-Strand cDNA labeling kit (which inherently produces Cy5-dCTP or Cy3-dCTP to label cDNA produced from RNA) (p.11 – Red-white muscle microarray hybridisation), an Affymetrix 428 scanner (p.11 – Red-white muscle microarray hybridization, second paragraph), which is a fluorescent scanning system, and ImaGene v4.2 and GeneSpring v4.2 (p.11 – Microarray expression analysis and clone identification) which are computer analysis systems for analysis of swine genes.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (1995) (US Patent 5,474,796) in view of Li et al (2001).

Regarding claim 1, from which claim 3 depends, Brennan teaches a microarray that contains 10-mer polynucleotides spotted at a discrete location such that the total array represents every possible permutation of 10-mer oligonucleotide (col. 9, lns. 48-55). Such an array would inherently comprise probes capable of detecting genes expressed in swine. The array of Brennan would inherently be capable of detecting genes, including any 'growth specific' genes, expressed in the muscle and fat tissues of swine (relevant to claim 1).

Regarding the kit of claim 3, Brennan thus teaches a cDNA chip having growth specific genes of swine integrated thereon.

Brennan et al does not teach Cy5-dCTP or Cy3-dCTP bound cDNA from RNA, a fluorescence scanning system, and a computer analysis system.

Li et al teaches an analysis of genetic material using microarrays. The reference teaches probe material labeled using Cy5-dCTP and/or Cy3-dCTP in an RT-PCR reaction (p.697 – Probe preparation and multiplex PCR) (thus Cy5-dCTP or Cy3-dCTP labeled cDNA from RNA), as well as a fluorescence scanning system (i.e. confocal scanners), and a computer analysis system (i.e. ImaGene software) (p.697 – Hybridization and data analysis).

It would have been prima facie obvious to one of skill in the art at the time the invention was made to have combined the array of Brennan with the Cy5-dCTP or Cy3-dCTP labeled cDNA from RNA, fluorescence scanning system, and a computer analysis

system of Li et al to have created the kit of the claim 3 of the instant application. One would have been motivated to do so based on the assertion of Li et al that such methods allow for the differentiation of amplified molecules in complex mixtures (p696 – Abstract).

14. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yao et al (2002) in view of Li et al (2001).

Regarding claim 1, from which claim 3 depends, Yao et al teaches that RNA was isolated from the skeletal muscle of pigs, amplified by RT-PCR, and then the collection of fragments was cloned into a plasmid vector (p.213, lns.12-23). The reference also teaches the analysis of the cDNAs by Southern blot analysis. Yao et al teaches that aliquots of plasmid DNA from the library are digested to liberate the insert, separated on a 1% agarose gel, then blotted onto a Zeta-probe membrane (p.214 – Southern blot analysis; p.215, last paragraph). The membrane containing the separated library (Fig 1) is thus a cDNA chip (i.e. a substrate upon which cDNA probes are immobilized). The immobilized probes include a mixture of probes derived from swine, and would thus be comprised of probes suitable for the screening and analysis of 'growth specific' genes expressed in tissues of swine..

Regarding the kit of claim 3, Yao et al thus teaches a cDNA chip having growth specific genes of swine integrated thereon.

Yao et al does not teach Cy5-dCTP or Cy3-dCTP bound cDNA from RNA, a fluorescence scanning system, and a computer analysis system.

Li et al teaches an analysis of genetic material using microarrays. The reference teaches probe material labeled using Cy5-dCTP and/or Cy3-dCTP in an RT-PCR reaction (p.697 – Probe preparation and multiplex PCR) (thus Cy5-dCTP or Cy3-dCTP labeled cDNA from RNA), as well as a fluorescence scanning system (i.e. confocal scanners), and a computer analysis system (i.e. ImaGene software) (p.697 – Hybridization and data analysis).

It would have been prima facie obvious to one of skill in the art at the time the invention was made to have combined the immobilized probes of Yao et al with the Cy5-dCTP or Cy3-dCTP labeled cDNA from RNA, fluorescence scanning system, and a computer analysis system of Li et al to have created the kit of the claim 3 of the instant application. One would have been motivated to do so based on the assertion of Li et al that such methods allow for the differentiation of amplified molecules in complex mixtures (p696 – Abstract).

### *Claim Rejections - 35 USC § 101*

15. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

16. Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to a cDNA chip for screening and function analysis of growth specific genes in swine. The specification asserts that the claimed invention

would be applied to swine improvement and the breeding of a new breed (p.4; p.14). However, the specification does not disclose how such objective (swine improvement or the breeding of a new breed) would be accomplished thought the use of the claimed invention. Additionally, there is no teaching in the specification, nor any indication in the prior art, as to how a cDNA chip of the instant claims, or an analysis of the expression of SEQ ID NOs 1-5 (recited in the cDNA chip of claim 5), would in be specifically informative with regard to swine improvement, breeding new breeds, or be indicative of any useful phenotype. Furthermore, examination of SEQ ID NOs 1-5 (of claim 2) indicates similarity to genes from both swine and heterologous organisms (e.d SEQ ID NO: 1 has similarity to a mouse elongation factor), for which there is no teaching in either the specification or the prior art as to what sort of analysis of expression would be required to draw any conclusion concerning any of the asserted objectives of the claimed invention.

Therefore, the asserted utilities of swine gene analysis (i.e. a cDNA chip comprising a probe comprising growth specific genes) ar not considered specific or substantial, as the claimed cDNA chip, even with probes comprising SEQ ID NOs 1-5 would not provide information that is biologically relevant with regard to the asserted utilities. Thus, there would be a burden on the artisan using the claimed product for the analysis swine gene expression to determine a specific and substantial utility for data generated by the analysis of swine gene expression using the claimed invention. The asserted utilities, therefore, do not constitute a substantial utility for the claimed

invention, since further experimentation would be required to establish a real world use for the claimed invention.

Claims 1-3 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Double Patenting***

17. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

18. Claim 2 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 9 of copending Application No. 10/789,723. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 1 and 3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/785,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope and subject matter.

Regarding claim 1 of the instant application, the claims of the conflicting application are drawn to a cDNA chips (claims 1-4) and a kit comprising the same chip (claim 5) comprising probes directed to genes expressed in the muscle and fat tissues of swine. The muscle specific cDNA chip of claim 1 of copending Application 10/785,576 would include the growth specific genes of the claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. Claims 1 and 3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/788,562. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope and subject matter.

Regarding claim 1 of the instant application, the claims of the conflicting application are drawn to a cDNA chips (claims 1 and 2) and a kit comprising the same chip (claim 3) comprising probes directed to genes expressed in the muscle and fat tissues of swine. The fat specific cDNA chip of claim 1 of copending Application 10/785,562 would include the growth specific genes of the claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/789,723. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope and subject matter.

Regarding claim 1 of the instant application, the claims of the conflicting application are drawn to cDNA chips directed to genes expressed in the muscle and fat tissues of swine. The cDNA chip of the copending Application 10/789,723 would include the growth specific genes of the claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. Claim 3 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 10 of copending Application No. 10/789,723 in view of Li et al (2001).

Claim 10 of the conflicting application is drawn to a kit comprising a cDNA chip with probes for detecting genes specifically expressed in the muscle and fat tissues of swine. Such a chip would include the growth specific genes of the claims of the instant application. The kit of the conflicting application does not specifically include Cy5-dCTP or Cy3-dCTP bound cDNA from RNA, a fluorescence scanning system, and a computer analysis system. However these components of a kit for gene analysis were well known in the art at the time the invention was made.

Li et al teaches an analysis of genetic material using microarrays. The reference teaches probe material labeled using Cy5-dCTP and/or Cy3-dCTP in an RT-PCR reaction (p.697 – Probe preparation and multiplex PCR) (thus Cy5-dCTP or Cy3-dCTP labeled cDNA from RNA), as well as a fluorescence scanning system (i.e. confocal scanners), and a computer analysis system (i.e. ImaGene software) (p.697 – Hybridization and data analysis).

It would have been prima facie obvious to one of skill in the art at the time the invention was made to have combined the immobilized probes of the conflicting application (10/789,723) with the Cy5-dCTP or Cy3-dCTP labeled cDNA from RNA,

fluorescence scanning system, and a computer analysis system of Li et al to have created the kit of the claim 3 of the instant application. One would have been motivated to do so based on the assertion of Li et al that such methods allow for the differentiation of amplified molecules in complex mixtures (p696 – Abstract).

This is a provisional obviousness-type double patenting rejection.

### *Conclusion*

No claim is allowable. No claim is free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen Kapushoc
Art Unit 1634

JULIET C. SWITZER
PRIMARY EXAMINER